



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

88450-1

Date of Issuance:

8/5/15

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

LuminOre Copper Touch
Antimicrobial Surfaces

Name and Address of Registrant (include ZIP Code):

LuminOre Inc.
6060 Corte del Cedro
Carlsbad, CA 92011

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Julie Chao, Product Manager 33
Regulatory Management Branch 1, Antimicrobials Division (7510P)

Date:

8/5/15

2. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. Copper GDCI-022501-1258

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Comply with the following, additional terms of registration:

Term 1

LuminOre will prepare and implement a LuminOre Copper Touch Antimicrobial Surfaces Stewardship Plan (“the Plan”) designed to support the responsible use of antimicrobial copper products. The Plan will be submitted for EPA review and approval within two months after the registration date. If EPA determines at any time after 18 months following registration that the Plan is not being adequately or timely implemented or that implementation of the Plan is not effectively ensuring the proper sale, distribution, or use of antimicrobial copper products, the registration may be automatically cancelled by the Agency by order with no opportunity for a hearing but only after notification to the Registrant and an opportunity to meet with the Director of the Office of Pesticide Programs.

The Plan will include, at a minimum, the following elements:

- (a) Outreach to the infection control community, including:
 - (i) A goal of educating and reinforcing, for infection control professionals and other product users, the proper use of LuminOre Copper Touch Antimicrobial Surfaces.
 - (ii) Written (including electronic) communications directed to associations of infection control professionals, including at the least APIC, ASHES, and any other relevant organizations identified by CDA or EPA, and State Departments of Health.
 - (iii) Outreach communications will be sent within six months after the date of registration and within one year after the date of registration, and then annually thereafter on the anniversary of the date of the registration unless more frequent outreach is deemed necessary.
 - (iv) The content of the outreach communications will include statements explaining the registered claims and applications of LuminOre Copper Touch Antimicrobial Surfaces, as well as their proper use. The communications also will inform the recipients about (1) the LuminOre Copper Touch Antimicrobial Surfaces WorkGroup (see below) and invite their participation; (2) other sources of information on LuminOre Copper Touch Antimicrobial Surfaces, including the Stewardship Website (see below). Additional content of outreach efforts will be developed as part of the Working Group activities.
- (b) Development of a Stewardship Website (“the Website”) under the auspices of the LuminOre Incorporated.

- (i) The Website will serve as a resource for conveying accurate information to the public about the efficacy and proper use of LuminOre Copper Touch Antimicrobial Surfaces.
 - (ii) The Website will include information on proper labeling and claims (including advertising); supporting science; applications; maintenance; and federal and state regulations and statutory requirements.
 - (iii) A question and answer or Frequently Asked Questions (FAQs) section will be incorporated to address common issues or questions raised with regard to LuminOre Copper Touch Antimicrobial Surfaces.
 - (v) Links will be arranged and established by LuminOre between the Stewardship Website and the websites of appropriate infection control organizations, including but not limited to APIC and ASHES.
- (c) Establishment of a LuminOre Copper Touch Antimicrobial Surfaces Working Group (“the Working Group”).
- (i) Invited participants will include component makers, and representatives from the infection control community, including appropriate trade associations (e.g., APIC and ASHES) and State Departments of Health.
 - (ii) The Working Group will meet at least twice a year, either in person or by live video conferencing (WEBEX) or teleconferencing.
 - (iii) The Working Group will serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community.
 - (iv) LuminOre shall provide EPA with minutes of any such meetings within 60 days of the end of any such meeting.

Term 2

For at least the first 24 months after registration or until the Agency terminates this condition, whichever is later, LuminOre will submit to EPA sample advertising materials. Advertising materials will be representative of advertisements intended for use in the marketplace.

4. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those

claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 07/29/2015

If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at Leavy.Karen@epa.gov.

Sincerely,



Julie Chao, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Enclosure

Master Label Containing

Sublabel 1. Complete Label

Sublabel 2. Hang Tag Label

Sublabel 1. Complete Label

**LuminOre Copper Touch Antimicrobial Surfaces
Antimicrobial Copper
Surface Active Product**

ACTIVE INGREDIENT:

Copper*85.0%

OTHER INGREDIENTS:15.0%

TOTAL 100.00%

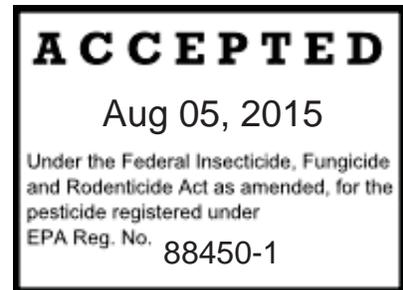
*Contain 3.8 oz. of copper per ft²

EPA Reg. No.: 88450-1

EPA Est. No.: XXXXX-XX-XXX

Net Wt.: XX

LuminOre, Incorporated
6060 Corte del Cedro
Carlsbad, CA 92011



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

(Note: The surface of this product contains copper, which functions as an antimicrobial agent. Product types that can be sold pursuant to this label are listed below. None of these product types are approved for direct food contact or food packaging uses).

Touch Surface Components

Healthcare Facilities

- Bedrails, footboards
- Toilet seats
- Flush handles
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
 - Hospital carts (table surfaces, handles, legs)
 - Computer carts
 - Record carts
 - Phlebotomy carts
 - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars
- Countertops and tabletops (non-food use only)
- Door pulls,
- Toilet and urinal hardware, levers, push buttons
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames

- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Wall tiles
- Instrument handles
 - Medical equipment knobs, pulls and handles for:
 - Drug delivery systems
 - Monitoring systems
 - Hospital beds
 - Office equipment
 - Operating room equipment
 - Stands and fixtures
 - Types of knobs: e.g., Prong, fluted, push/pull, T-handle, tapered, and ball knobs
- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles
- Critical care cart: Table top, drawer, drawer pull,
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- Electrical wallplates

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Toilet seats
- Flush handles
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Light switches, switch plates

- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, handles, cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Toilet seats
- Flush handles
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Countertops and tabletops (non-food use only)
- Door pulls
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Television remote
- Magazine rack
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Monitor (television, computer, etc.) housing

Mass Transit Facilities

- Handrails

- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews

STORAGE AND DISPOSAL

Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

Sublabel 2. Hang Tag Label

(Note: The product types listed above may be sold and distributed under EPA Registration Number 88450-X. These products must bear the label below, with one or more of the listed claims.

FRONT PANEL

LuminOre Copper Touch Antimicrobial Surfaces	
Active Ingredient:	
Copper*	85.0%
Other.....	15.0%
[Total	100.0%]
See [Back/Side Panel][Insert] for Directions for Use	
NET WEIGHT:	lbs [brand name]
*Contains 3.8 oz. of copper per ft2	

BACK/INSERT PANEL

<p style="text-align: center;">LuminOre Copper Touch Antimicrobial Surfaces</p> <p>Laboratory testing has shown that when cleaned regularly this surface:</p> <ul style="list-style-type: none">- Continuously reduces bacterial* contamination, achieving 99.9% reduction within 2 hours of exposure.- Kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.- Delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.- Kills greater than 99.9% of bacteria* within 2 hours and continues to kill 99% of bacteria* even after repeated contaminations.- Helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.- This product continuously kills bacteria left behind [by dirty hands][on the surface] killing more than 99.9% of bacteria within 2 hours. <p>* <i>Staphylococcus aureus</i>, <i>Enterobacter aerogenes</i>, <i>Methicillin-Resistant Staphylococcus aureus (MRSA)</i>, <i>Escherichia coli 0157:H7</i> and <i>Pseudomonas aeruginosa</i></p> <p style="text-align: center;">DIRECTIONS FOR USE</p> <p>It is a violation of Federal law to use this product in a manner inconsistent with its labeling. <i>Proper Care and Use. (The following paragraph should appear on items intended to be used in health care facilities)</i>Clean and sanitize according to standard practice. Healthcare facilities must maintain the product in accordance with infection control guidelines. The use of this surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. This surface has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.</p> <p>This surface may be subject to recontamination and the level of active bacteria at any time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order to have proper antimicrobial effect, this product must be cleaned and maintained according to the directions for use.</p> <p>Do not wax, paint, lacquer, varnish, or otherwise coat this product.</p> <p>Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touch surfaces are permissible. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of this surface will not impair antibacterial effectiveness.</p> <p>Not approved for direct food contact or food packaging uses.</p> <p>[Items exposed to outdoor environmental conditions are not representative of indoor laboratory test conditions, and, therefore, may impart reduced efficacy if not cleaned when visibly soiled.]</p> <p style="text-align: center;">STORAGE AND DISPOSAL</p> <p>Dispose of by recycling or put in trash.</p> <p style="text-align: center;">WARRANTY STATEMENT</p> <p>If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.</p> <p>EPA Reg. No. 88450-1 EPA Est. No. XXXX- Manufactured by: LuminOre, Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011</p>
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